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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/814,194	04/01/2004	Johan Frostegard	FROSTEGARD=1C	6446

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EXAMINER	
COOK, LISA V	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 06/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/814,194	FROSTEGARD, JOHAN	
	Examiner	Art Unit	
	Lisa V. Cook	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 March 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9 and 11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9 and 11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/720,967.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/2/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Amendment Entry

1. Applicant's response to the Office Action mailed December 29, 2005 is acknowledged (paper filed 3/29/06). In the amendments filed therein claim 1 was modified. Claims 10 and 12-23 have been canceled. Currently claims 1-9 and 11 are pending and under consideration.

2. Objections and/or rejections of record not reiterated below have been withdrawn.

NEW GROUNDS OF REJECTIONS

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

I. Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barquinero et al. (Lupus, 1994, 3, 55-58) in view of Muzya et al. (Immunologiya, 1997, Vol.6, pages 9-11, Abstract Only).

Barquinero et al. teach an ELISA assay to measure antibodies against platelet-activating factor (PAF) in patients with autoimmune diseases. Specifically blood samples from patients with SLE (systemic lupus crythematosus), PAPS (antiphospholip syndrome), and syphilis were employed. See abstract and page 55 Introduction and page 56 "ELISA technique for anti-PAF".

Although Barquinero et al. teach the reagents required by the claims; they do not specifically teach the use of antibodies to PAF to evaluate spontaneous abortion.

However, Muzya et al. teach that antibodies involving the ligand phosphatidylcholine (antiphosphatidylcholine antibodies) bind to PAF, lyso-PAF, and acyl analogs of PAF. The binding of antiphosphatidylcholine antibodies to PAF and its structural analogs is related to the presence of phosphocholine fragments. The binding of antiphosphatidylcholine antibodies to PAF was exemplified in the sera of women with obstetrical-gynecological disorders (reading on spontaneous abortions). See abstract.

It would have been prima facie obvious to one of ordinary skill in the art at the time of applicant's invention to take the anti-PAF detection assay methods as taught by Barquinero et al. and employ them to evaluate obstetrical-gynecological disorders such as spontaneous abortions as taught by Muzya et al. because Muzya et al. taught that antibodies to PAF (antiphosphatidylcholine antibodies) were elevated in sera samples of women with obstetrical-gynecological disorders. See abstract. Accordingly one having ordinary skill in the art would have been motivated to employ the measurement of antibodies to PAF to evaluate obstetrical-gynecological disorders or spontaneous abortions in order to detect/prevent/assess potential effects of said disorder.

II. Claims 9 and 11 are rejected under 35 U.S.C.103(a) as being unpatentable over Barquinero et al. (Lupus, 1994, 3, 55-58) in view of Muzya et al. (Immunologiya, 1997, Vol.6, pages 9-11, Abstract Only) and further in view of Baldo et al. (WO 87/05904).

Please see Barquinero et al. in view of Muzya et al. as set forth above.

Barquinero et al. in view of Muzya et al. differ from the instant invention in not specifically teaching phosphorylcholine and lysophosphatidylcholine antigens (ligands).

However, Baldo et al. teach antigenic analogues of PAF (ligands) that are used to generate antibodies that bind PAF or antibodies to an antigen that binds aPAF. See claim 1 lines 6-7. The ligands including phosphorylcholine and is disclosed in the examples beginning at page 16 of the disclosure. Lysophosphatidylcholine structures are taught on page 30, for example.

The use of these ligands is taught to be useful because PAF is insufficiently antigenic to produce the necessary PAF-antibodies needed for immunoassay. The novel synthetic analogues (including phosphorylcholine) were sufficient to produce PAF-antibodies, which are suitable for immunoassay of PAF levels in biological fluids. See page 2 lines 4-12.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the ligand phosphorylcholine or lysophosphatidylcholine as taught by Baldo et al. in view of Muzya et al. in the measurements of antibodies to PAF and/or antibodies to an antigen(PAF) that binds aPAF as taught by Barquinero et al. in view of Muzya et al. because Baldo et al. taught that PAF is insufficiently antigenic to produce the necessary PAF-antibodies needed for immunoassay. The novel synthetic analogues (including phosphorylcholine) were sufficient to produce PAF-antibodies, which are suitable for immunoassay of PAF levels in biological fluids. See page 2 lines 4-12.

Response to Arguments

4. Applicant's arguments against the references of O'Neil (US Patent #4,879,285) and Karasawa et al. are MOOT because the reference has been removed.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., naturally occurring levels of aPAF or endogenous aPAF) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. Please note, the claims do not distinguish between naturally occurring aPAF and synthetic aPAF. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicants argue that no motivation exists in Barquinero et al. to employ antibodies other than anti-PAF antibodies. This argument was carefully considered but not found persuasive because Barquinero et al. are cited in combination with Muzya et al. and Baldo et al. In particular, Muzya et al. and Baldo et al. disclose the use of antibodies other than anti-PAF antibodies. Muzya et al. teach that antibodies involving the ligand phosphatidylcholine (antiphosphatidylcholine antibodies) bind to PAF, lyso-PAF, and acyl analogs of PAF. See abstract. While, Baldo et al. teach antigenic analogues of PAF (ligands) that are used to generate antibodies that bind PAF or antibodies to an antigen that binds aPAF. See claim 1 lines 6-7. One of ordinary skill would have been motivated to use these ligands because Baldo et al. taught that PAF is insufficiently antigenic to produce the necessary PAF-antibodies needed for immunoassay. The novel synthetic analogues (including phosphorylcholine) were sufficient to produce PAF-antibodies, which are suitable for immunoassay of PAF levels in biological fluids. See page 2 lines 4-12.

While a deficiency in a reference may overcome a rejection under 35 USC 103, a reference is not overcome by pointing out that a reference lacks a teaching for which other references are relied. In re Lyons, 364 F.2d 1005, 150 USPQ 741, 746 (CCPA 1966).

In response to the arguments that the use of phospocholine, phosphorylcholine and/or lysophophosphatidylcholine as a ligand provided for a more specific group of antibodies, it is noted that Baldo et al. teach the production of antibodies with these ligands. Accordingly, attorney's arguments of unexpected results cannot take the place of evidence in the record.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

5. For reasons aforementioned, no claims are allowed.

Remarks

6. Prior art made of record and not relied upon is considered pertinent to the applicant's disclosure:

A. Baldo et al. (LIPIDS, Vol26, No.12, 1991, 1136-1139) teach an immunoassay technique to measure PAF

7. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Group 1641 – Central Fax number is (571) 273-8300, which is able to receive transmissions 24 hours/day, 7 days/week. In the event Applicant would like to fax an unofficial communication, the Examiner should be contacted for the appropriate Right Fax number.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa V. Cook whose telephone number is (571) 272-0816. The examiner can normally be reached on Monday - Friday from 7:00 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (571) 272-0823.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see httpr//pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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6/6/06

LONG V. LE
SUPERVISORY PATENT EXAMINER
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06/09/06